2. (Amended) Use of the test as claimed in claim 1 wherein the method comprise the steps of:

a) taking a sample from each participant or potential participant in a clinical drug trial,

b) screening the samples for the genetic basis of Gilbert's Syndrome,

c) identifying such participants having the genetic basis of Gilbert's Syndrome, and

d) proceeding with the clinical drug trial based on the knowledge of such participants possessing or not possessing the genetic basis of Gilbert's Syndrome.

C1 cont

3. (Twice Amended) Use of the test as claimed in claim 1 wherein the sample is chosen from blood, buccal smear or any other sample containing DNA from the participants or potential participants.

C2

4. (Twice Amended) Use of the test as claimed in claim 1 wherein the method further comprises the step of eliminating participants having the genetic basis of Gilbert's Syndrome from the clinical drug trial.

5. (Twice Amended) Use of the test as claimed in claim 1 wherein the method further comprises the step of selecting only participants having the genetic basis for Gilbert's Syndrome for the clinical drug trial.

6. (Twice Amended) Use of the test as claimed in claim 1 further comprising the step of interpreting the results of the clinical drug trial based on the knowledge that certain participants have the genetic basis of Gilbert's Syndrome as distinguished from participants adversely affected by the drug.

C2 cont

7. (Twice Amended) Use of the test as claimed in claim 1 wherein the method comprises the steps of:

a) isolating DNA from each sample,

b) amplifying the DNA inner region indicating the genetic basis for Gilbert's Syndrome,

c) isolating amplified DNA fragments, and

d) identifying participants having the genetic basis of Gilbert's Syndrome.

8. (Twice Amended) Use of the test as claimed in claim 7 wherein the DNA is amplified using the polymerase chain reaction (PCR) using a radioactively labeled pair of nucleotide primers.

9. (Twice Amended) Use of the test as claimed in claim 7 wherein the DNA region indicating the genetic basis of Gilbert's Syndrome is the gene encoding UDP-glucuronosyltransferase (UGT).

10. (Twice Amended) Use of the test as claimed in claim 7 wherein the DNA to be amplified is in an upstream promoter region of the UGT 1*1 exon 1.

C 2 cont

11. (Twice Amended) Use of the test as claimed in claims 7 wherein the DNA to be amplified includes the regions between -35 and -55 nucleotides at the 5' end of UGT 1*1 exon.

12. (Twice Amended) A kit for screening participants or potential participants in clinical drug trials, wherein the kit comprises primers for amplifying DNA in the region of the genome indicating the genetic basis of Gilbert's Syndrome.

13. (Twice Amended) Primers for use of the test as claimed in claim 1 including primer pairs, AB or CD as follows:

A/B: (A,5' - AAGTGAACTCCCTGCTACCTT-3' (SEQ ID NO:1),

B,5' -CCACTGGATCAACAGTATCT-3' (SEQ ID NO:2) or

C/D: (C,5' -GTCACGTGACACAGTCAAAC-3' (SEQ ID NO:3);

D 5' -TTTGCTCCTGCCAGAGGTT-3' (SEQ ID NO:4)).

A. Brief Summary of the Present Invention

The present invention relates to a method for improving the efficacy of clinical drug trials. Specifically, the method of the present invention can be used to screen samples containing DNA from potential participants or